REMARKS

Claims 32-36 and 39-47 are currently pending in this application. By the present amendment, Claims 36 and 39-42 have been amended and Claims 43-54 have been added. In view of the amendments and remarks to follow, allowance of this application is respectfully requested.

In the Office Action, Claims 32-36 and 39-42 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,835,199 to McGuckin, Jr. et al. ("McGuckin") in view of U.S. Patent No. 5,897,562 to Bolanos et al. ("Bolanos").

The present application discloses that pre-clamping the anvil assembly 110 and cartridge assembly 200 onto tissue before the staples are ejected from the cartridge assembly forces fluid from within the tissue to flow away from the anvil assembly 110 and cartridge assembly 200. Then, the dynamic clamping member further clamps tissue, without the impediment of the fluid pressure, maintaining the gap at the location where staples are being deployed, and continues to clamp as the dynamic clamping member travels down the anvil assembly 110 and cartridge assembly 200. The dynamic clamping member maintains the position of the anvil assembly 110 and cartridge assembly 200 as the staples are being fired. See pages 24 through 25 of the present application. A flexible member attached to the dynamic clamping member and separate from the pre-clamping member is used to advance the dynamic clamping member. Since the dynamic clamping member is not required to pre-clamp the anvil assembly 110 and cartridge assembly 200, forcing fluid away, a smaller flexible member can be utilized. The flexible member reduces firing forces in an articulating version (a version where the anvil assembly 110 and cartridge assembly 200 can pivot laterally) of the stapler where the flexible member is required to bend

around a pivot point during firing.

Independent Claim 32 requires a tool assembly comprising, *inter alia*, "a clamp collar ... to effect movement of the anvil in relation to the cartridge assembly from the open position towards the approximated position" and a "dynamic clamping member being configured to slidably engage the anvil and the cartridge assembly to define a maximum tissue gap between the anvil and the cartridge assembly adjacent the dynamic clamping member during ejection of the plurality of staples from the cartridge assembly."

McGuckin discloses a stapling apparatus 10 including a handle portion 12, an elongated flexible body portion 14, and a curved stapling assembly 16. The stapling assembly 16 includes a pair of opposable jaws 17 (FIG. 3). The jaws 17 are capable of being grossly approximated by actuation of actuator knob 38 (FIG. 3), which causes an actuation cable 44 (FIG. 12) to pull one jaw towards the other. McGuckin discloses two distinct embodiments to finely approximate the jaws 17 and to eject staples.

In one embodiment, illustrated in FIGS. 3 and 13-15, reproduced below, McGuckin uses an I-beam member 70 to finely approximate the jaws 17 and to eject staples. In this embodiment, actuation of a portion of the handle portion 12 "causes the I-beam member 70 to move through the stapling assembly 16 to sequentially fire arcuate rows of staples... When the I-beam member 70 is driven by the pusher 80, the sloped leading edge of the upper beam portion 82a contacts sequentially each of a plurality of staple pushers 118 to drive them through their respective staple slots." (Column 6, lines 12-25.) Additionally, as shown in FIGS. 13 and 15, each of the staple carrying portion 40 and the staple forming surface 50 includes a slot for allowing an upper beam portion 82a and a lower beam portion 82b, respectively, of the I-beam member 70 to pass

therethrough.

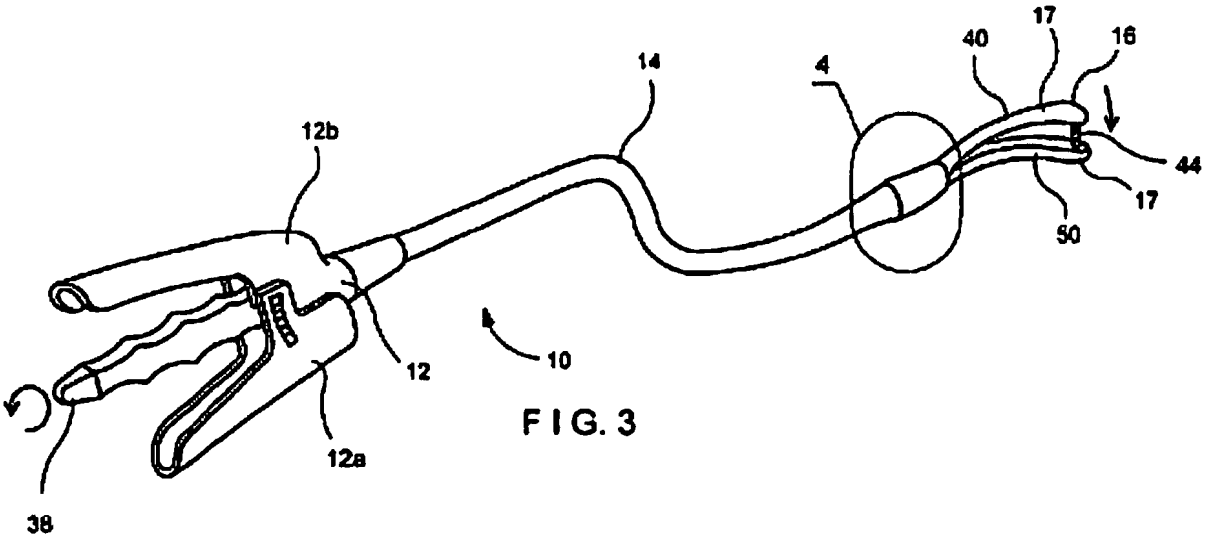


FIG. 3

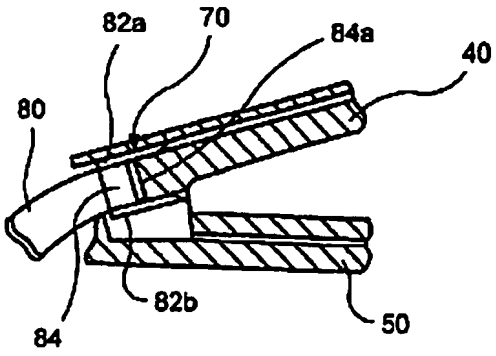


FIG. 13

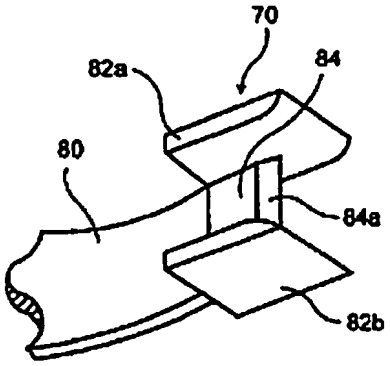


FIG. 14

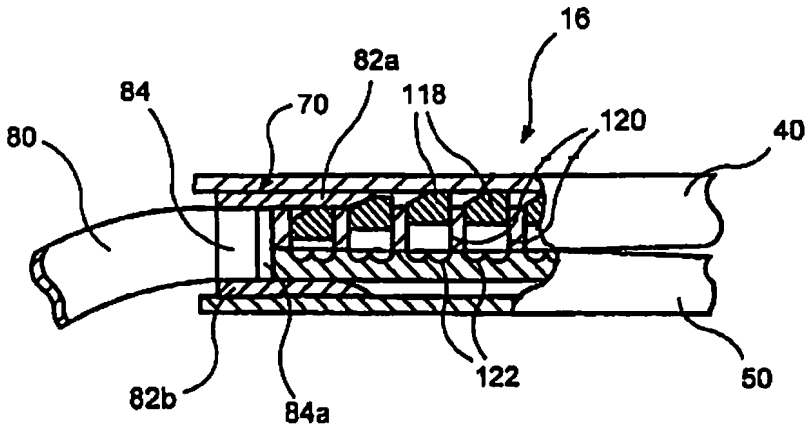


FIG. 15

In another distinct embodiment of McGuckin, illustrated in FIGS. 5 and 16-18, a C-shaped clamp member 60 is used to finely approximate the jaws 17 and to eject staples. In this embodiment, actuation of a portion of the handle portion 12 "causes the C-shaped clamp member 60 to move along an arc the length of the curved stapling assembly 16 to finely approximate the jaws 17 toward one another." (Column 5, lines 50-54.) Also shown in FIGS. 16 and 17, the "body 112 includes a radially depending driving stem 115 having a sloped leading edge configured to extend through an arcuate slot 116 formed in the staple carrying portion 40 for sequentially contacting each of a plurality of staple pushers 118." (Column 5, lines 60-64.) That is, in this embodiment of McGuckin, distal advancement of the C-shaped clamp member 60 causes fine adjustment of the jaws 17 relative to one another and causes ejection of staples.

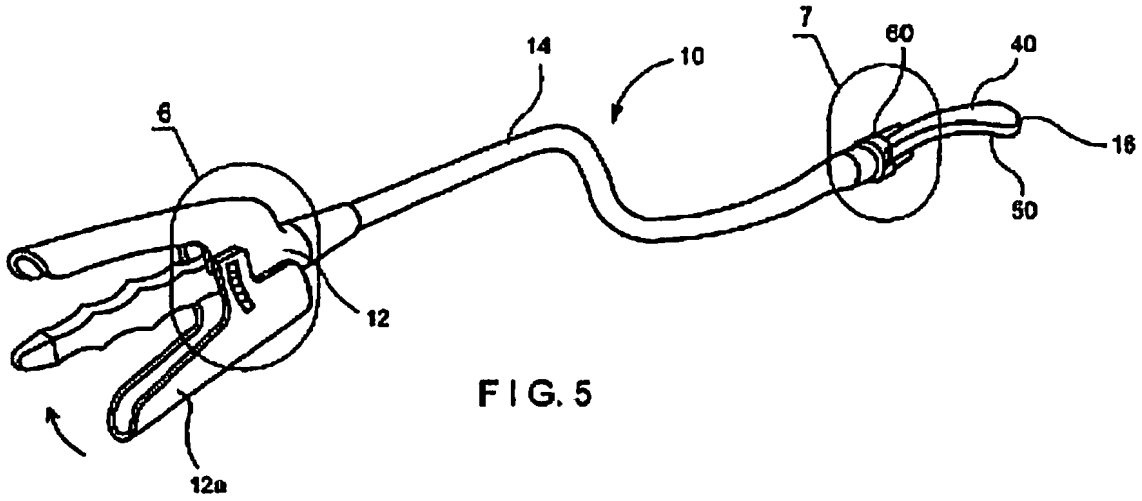


FIG. 5

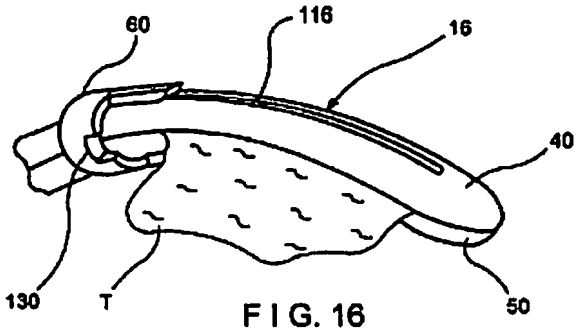


FIG. 16

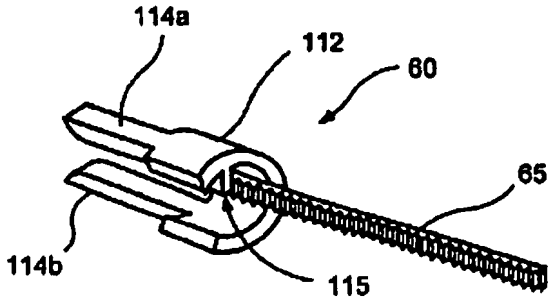


FIG. 17

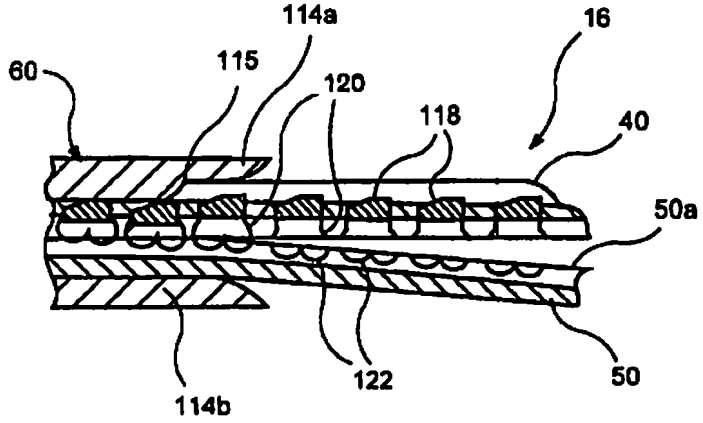


FIG. 18

In the Office Action, it was asserted that McGuckin discloses a tool assembly comprising,

inter alia, a clamp collar 60 to effect movement of the anvil in relation to the cartridge, *and* a dynamic clamping member 70 configured to slidably engage the anvil and the cartridge assembly to define a maximum tissue gap therebetween. As discussed above, McGuckin discloses one embodiment including a tool assembly having a C-shaped clamp member 60 for approximating the jaw members and for ejecting staples, and a second, distinct embodiment where the tool assembly includes a cable to effect approximation and an I-beam member 70. Neither embodiment includes a clamp collar to effect movement of the anvil in relation to the cartridge assembly from the open position towards the approximated position *and* a dynamic clamping member configured to slidably engage the anvil and the cartridge assembly to define a maximum tissue gap between the anvil and the cartridge assembly adjacent the dynamic clamping member during ejection of the plurality of staples from the cartridge assembly.

Applicants also respectfully submit that it is not possible for McGuckin's tool assembly to include both a C-shaped clamp member 60 and an I-beam member 70. More particularly, and as described above, both the C-shaped clamp member 60 and the I-beam member 70 cause ejection of staples. As such, the "sloped leading edge" of the driving stem 115 of the C-shaped clamp member 60 is configured for "sequentially contacting each of the staple pushers 118" (Column 5, lines 60-64) while the "sloped leading edge" of the I-beam member's 70 upper beam portion 82a sequentially contacts each of a plurality of staple pushers 118 (Column 6, lines 17-20). Thus, it would be duplicative for a single device to include McGuckin's C-shaped clamp member 60 and its I-beam member 70. Furthermore, the reference teaches away from such a combination, as both structures could not be accommodated in the instrument and the C-shaped clamp member and I-beam member would interfere with one another.

Therefore, Applicants respectfully submit that the Examiner's reliance on McGuckin for teaching a single instrument that includes both a "a clamp collar ... to effect movement of the anvil in relation to the cartridge assembly from the open position towards the approximated position" and a "dynamic clamping member being configured to slidably engage the anvil and the cartridge assembly to define a maximum tissue gap between the anvil and the cartridge assembly adjacent the dynamic clamping member during ejection of the plurality of staples from the cartridge assembly," as required by Claim 32, is without merit.

In the Office Action, Bolanos was relied on to teach a surgical instrument including cables 32 that "are operatively connected to the staple drivers and to a pulley system 48 for the purposes of effecting movement of said drivers upon rotation of said pulley" (Page 3, paragraph 5). Bolanos does not teach an instrument that includes both a clamp collar and a dynamic clamping member, as required by Claim 32.

Accordingly, for at least these reasons, Applicants respectfully submit that Claim 32 is allowable under 35 U.S.C. §103(a) over McGuckin in view of Bolanos. Since Claims 33-36 and 39-42 depend from Claim 32 and contain all of the limitations of Claim 32, Applicants respectfully submit that the subject matter of each of Claims 33-36 and 39-42, as a whole, is also allowable under 35 U.S.C. §103(a) over McGuckin in view of Bolanos.

With additional regard to Claim 32, Applicants respectfully submit that Claim 32 is allowable under 35 U.S.C. §103(a) over McGuckin in view of Bolanos for at least the following additional reasons.

Bolanos discloses a non-invasive apparatus shown in FIGS. 1, 3, 4 and 6A reproduced below which includes a staple cartridge 24 and an anvil 26. A roller assembly 34 includes a

roller member 51. Roller assembly 34 is movable in a proximal direction via a wire or rod 36 to pivot anvil 26 towards staple cartridge 24. Staple ejectors 28 are linked to moveable trigger 20 by elongate firing cables 32 that are secured to staple ejectors 28 at one end, and are secured at the other end to pulleys 48. Additionally, proximal movement of the trigger 20 causes staple ejectors 28 to be moved proximally. (Column 5, lines 23-36.)

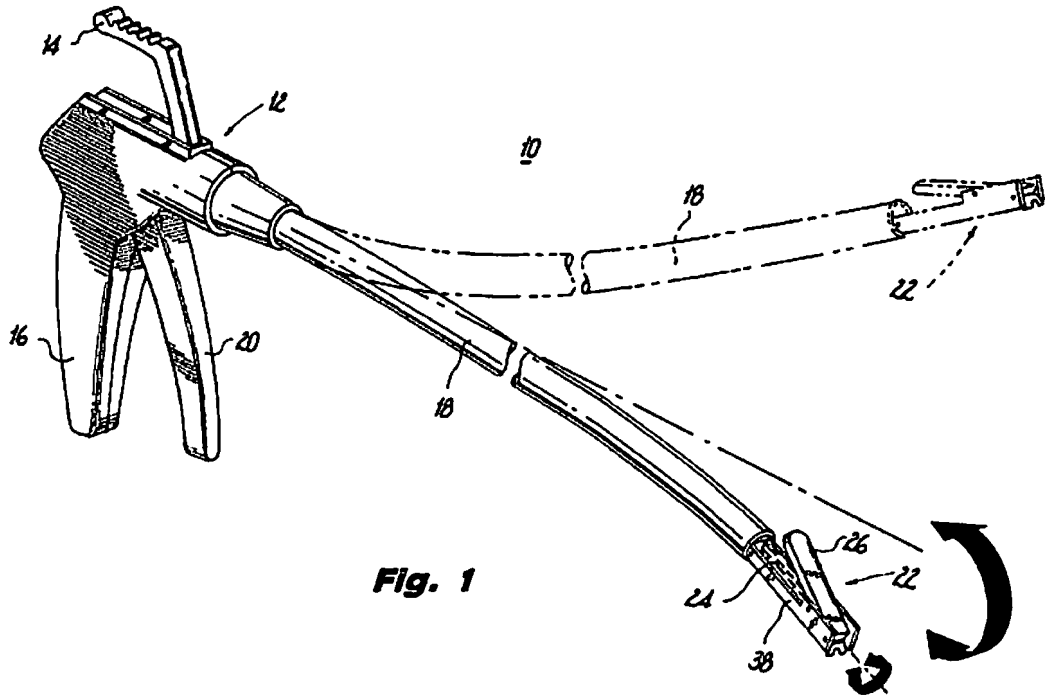


Fig. 1

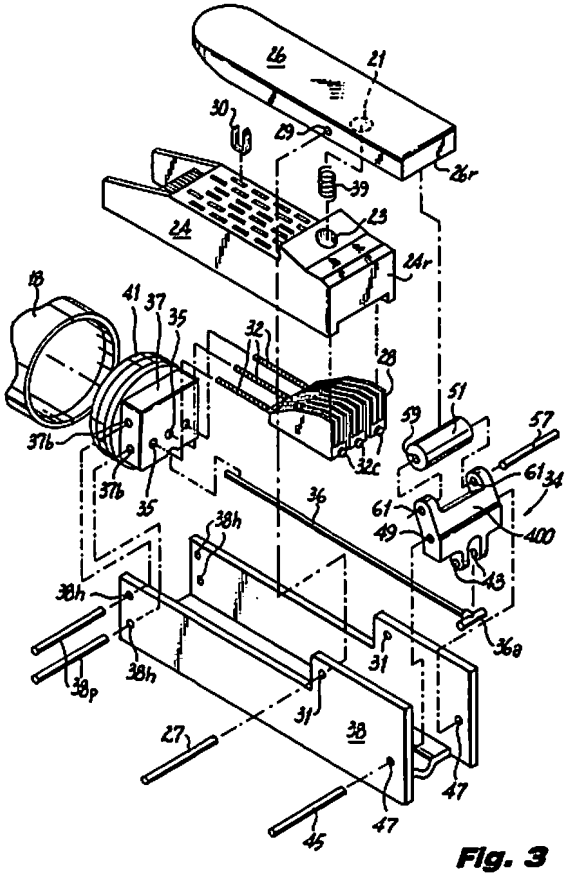


Fig. 3

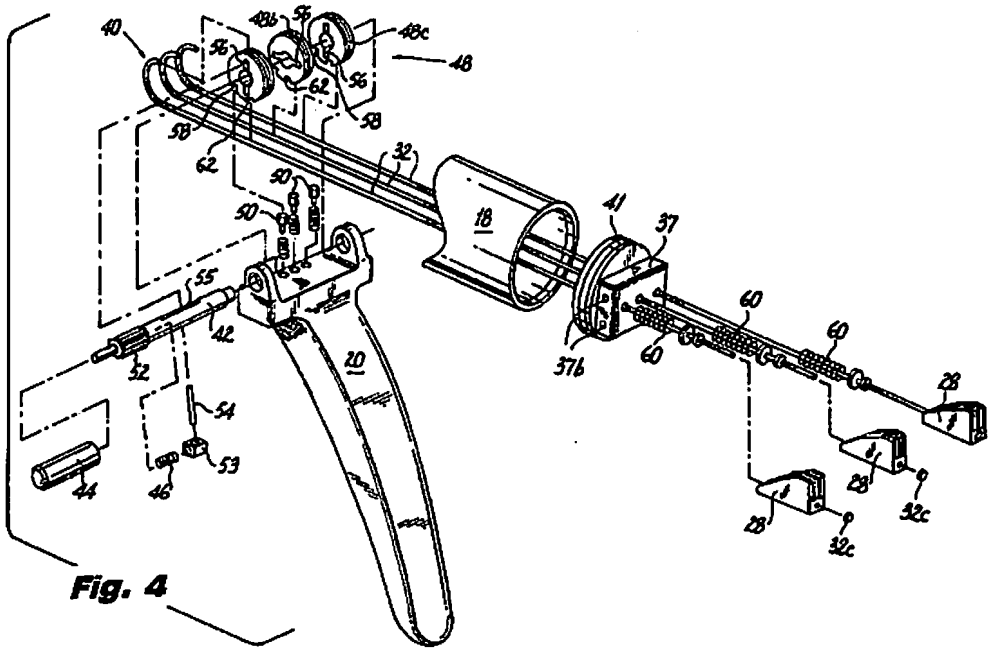
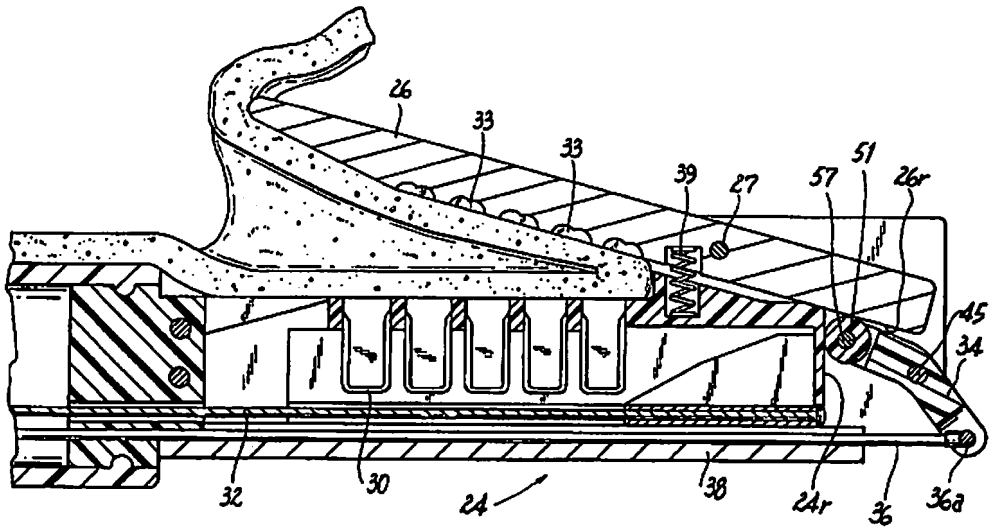


Fig. 4

Fig. 6A



Independent Claim 32 of the present application requires, a tool assembly comprising, *inter alia*, a "dynamic clamping member being configured to slidably engage the anvil and the cartridge assembly to define a maximum tissue gap between the anvil and the cartridge assembly adjacent the dynamic clamping member during ejection of the plurality of staples from the cartridge assembly" and "at least one pulley operatively associated with the dynamic clamping member to effect movement of the dynamic clamping member from the first position to the second position to effect ejection of staples from the cartridge assembly." That is, Claim 32 recites the functions performed (i.e., "engage the anvil and the cartridge assembly to define a maximum tissue gap" and "ejection of staples from the cartridge assembly") as a result of the dynamic clamping member moving from the first proximal position to the second distal position. Moreover, the member that slidingly engages the anvil and the cartridge assembly also effects ejection of the staples from the cartridge assembly.

In the Office Action, it is acknowledged that "McGuckin fails to disclose a pulley operatively associated with the flexible band 80 to effect the movement of the dynamic clamping

member" (See Paragraph 5). Bolanos was relied on to teach, *inter alia*, "cables are operatively connected to the staple drivers and to pulley system 48 for the purposes of effecting movement of said drivers upon rotation of said pulley." Further, it was asserted that the "substitution of one known element (a pulley as a power transmission means as shown in Bolanos) for another (a power transmission means as a gear rack and pinion, and drive cable as shown in McGuckin) would be been obvious."

Applicants have noted that neither McGuckin nor Bolanos teaches, discloses or even remotely suggests these limitations of Claim 32. For example, neither reference discloses "at least one pulley operatively associated with the dynamic clamping member." As stated above, and as quoted from the Office Action, "McGuckin fails to disclose a pulley operatively associated with the flexible band 80 to effect the movement of the dynamic clamping member." Additionally, while Bolanos may disclose a pulley system, the asserted pulley system of Bolanos is not "operatively associated with" a dynamic clamping member. Rather, the asserted pulley system of Bolanos is operatively associated with the staple ejectors 28. Thus, it is clear that neither reference discloses "at least one pulley operatively associated with the dynamic clamping member," as required by Claim 32. For at least this additional reason, Claim 32 is allowable under 35 U.S.C. §103(a) over McGuckin in view of Bolanos. Since Claims 33-36 and 39-42 depend from Claim 32 and contain all of the limitations of Claim 32, Applicants respectfully submit that the subject matter of each of Claims 33-36 and 39-42, as a whole, is also allowable under 35 U.S.C. §103(a) over McGuckin in view of Bolanos for at least this additional reason.

New Claims 43-47 also depend from Claim 32 and provide further distinctions over the references of record. For at least the reasons discussed above with respect to Claim 32,

Applicants submit that each of Claims 43-47 is also in condition for allowance.

Additionally, Independent Claim 48 has been added herein. Claim 48 is similar to Claim 32, but lacks the recitation relating to the "at least one pulley." As discussed hereinabove, Applicants respectfully submit that the "at least one pulley" limitation of Claim 32 is not necessary to distinguish from the art of record. For at least this reason, Claim 48 is in condition for allowance. Claims 49-54, each depending from Claim 48, have also been added herein. Applicants respectfully submit that the subject matte of each of Claims 49-54, as a whole, is allowable over the art of record for at least the reasons Claims 48 is allowable.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all claims pending in this application, namely Claims 32-36 and 39-54, are in condition for allowance. Accordingly, allowance of this application is respectfully requested. Should the Examiner feel that a telephone or personal interview may facilitate resolution of any remaining matters, she is respectfully requested to contact Applicants' attorney at the number indicated below.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

Respectfully submitted,

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